



(86) Date de dépôt PCT/PCT Filing Date: 2008/04/02
(87) Date publication PCT/PCT Publication Date: 2008/10/09
(85) Entrée phase nationale/National Entry: 2009/10/02
(86) N° demande PCT/PCT Application No.: US 2008/059114
(87) N° publication PCT/PCT Publication No.: 2008/122033
(30) Priorité/Priority: 2007/04/02 (US60/921,386)

(51) Cl.Int./Int.Cl. *A61B 1/018* (2006.01),
A61B 1/273 (2006.01)
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(54) Titre : APPAREIL ENDOSCOPIQUE AYANT UN RAIL EXTERNE
(54) Title: ENDOSCOPIC APPARATUS HAVING AN OUTER RAIL

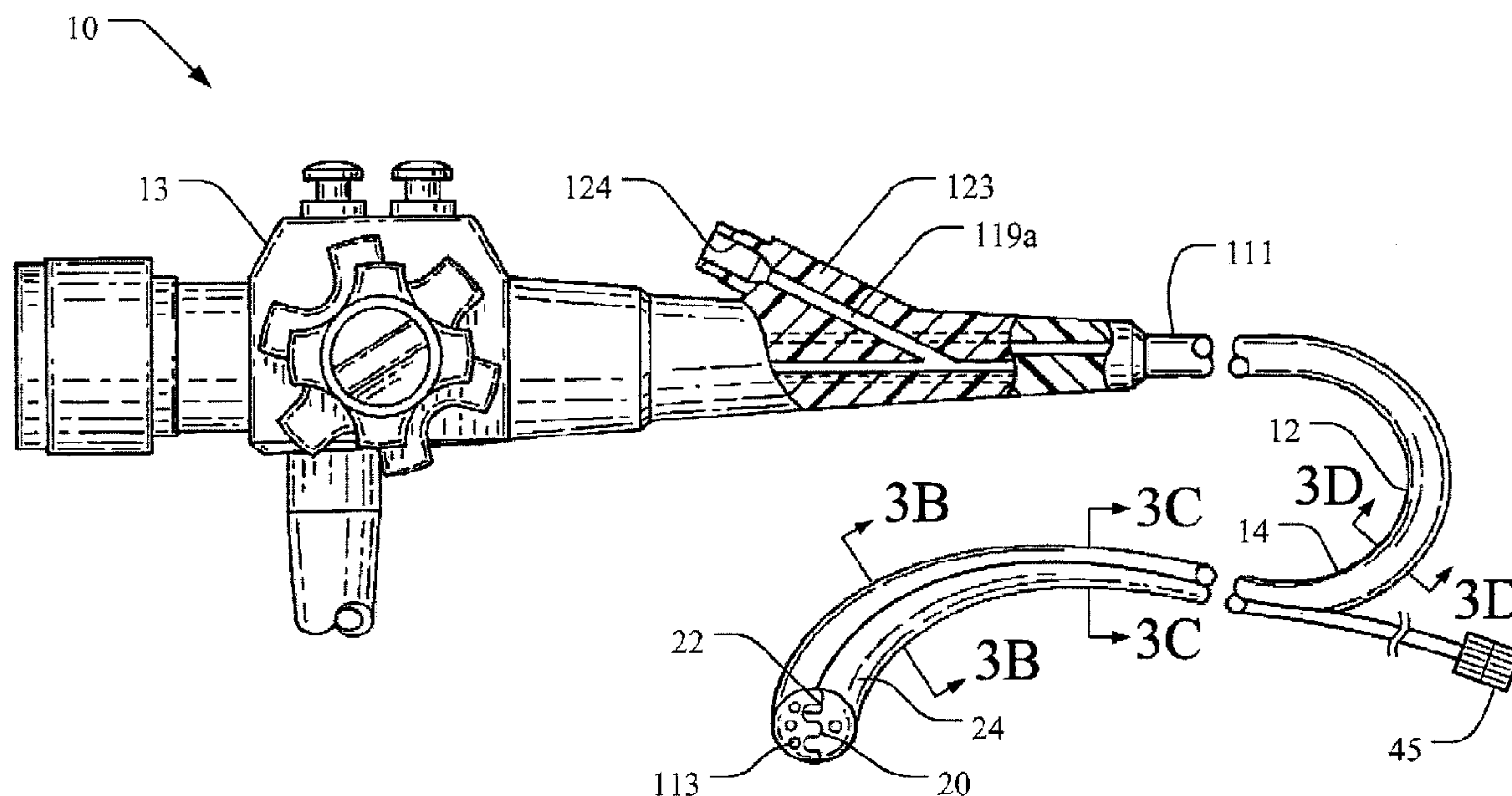


FIG. 1A

(57) **Abrégé/Abstract:**

An endoscope apparatus for endoscopic treatment is disclosed. The apparatus comprises an endoscopic insertion tube comprising an outer surface including an outer rail formed longitudinally thereon and extending along a portion of the insertion tube. The outer rail has a predetermined shape. The insertion tube comprises an inner channel formed therethrough. An endoscope apparatus for endoscopic treatment is disclosed. The apparatus comprises an endoscopic insertion tube without a working channel and an outer surface including at least one outer rail formed longitudinally thereon and extending along a portion of the insertion tube. The outer rail has a first predetermined shape. At least one medical device includes an outer wall having at least one mounting unit formed thereon along a portion of the length of the outer wall. The mounting unit has a second predetermined shape cooperable with the first predetermined shape. The second predetermined shape is formed to complement and slidably cooperate with the first predetermined shape of the outer rail for slidably attaching the medical device thereto.



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
9 October 2008 (09.10.2008)

PCT

(10) International Publication Number
WO 2008/122033 A1

(51) International Patent Classification:

A61B 1/018 (2006.01) A61B 1/273 (2006.01)

(21) International Application Number:

PCT/US2008/059114

(22) International Filing Date: 2 April 2008 (02.04.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/921,386 2 April 2007 (02.04.2007) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(54) Title: ENDOSCOPIC APPARATUS HAVING AN OUTER RAIL

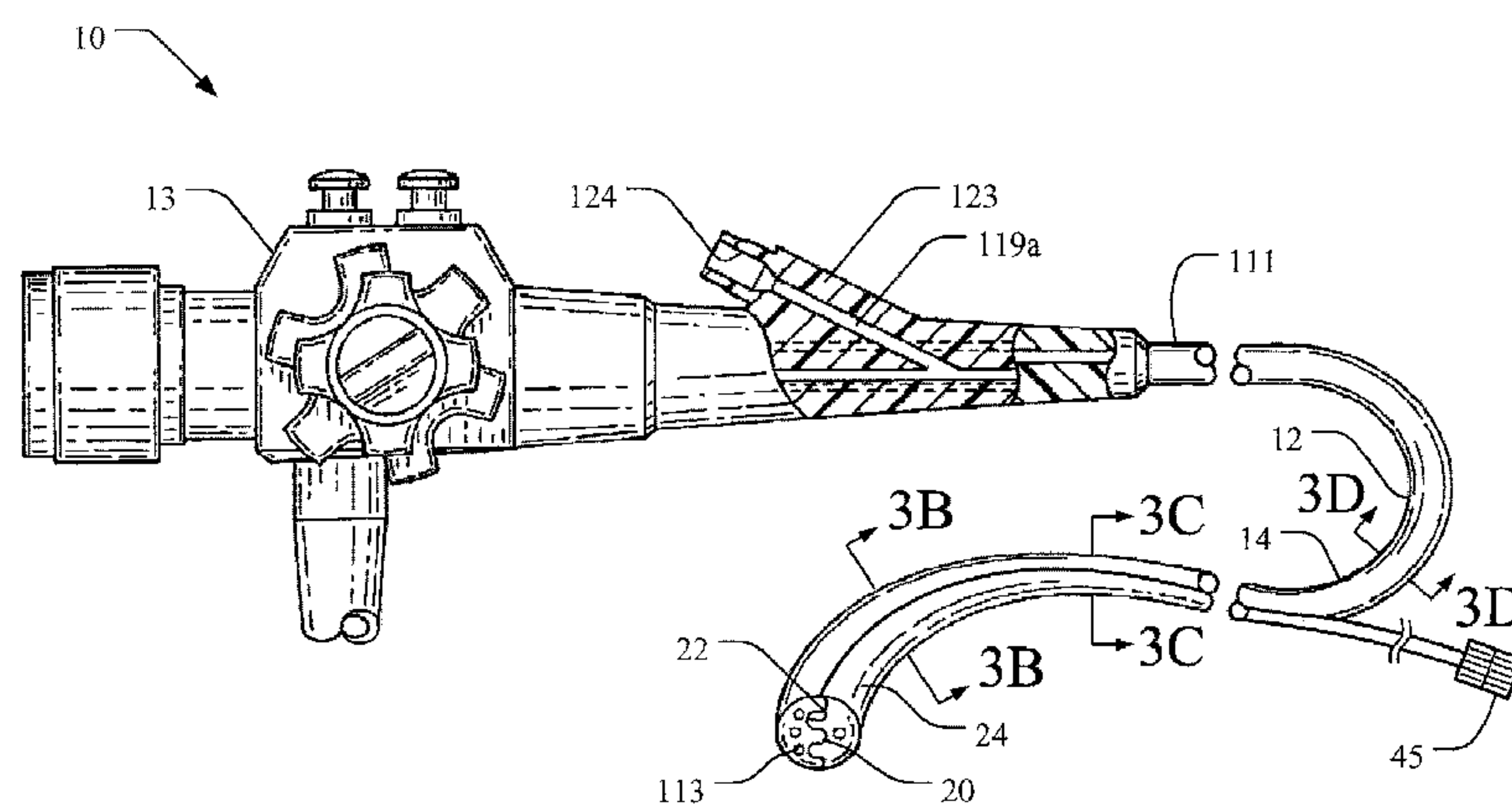


FIG. 1A

(57) Abstract: An endoscope apparatus for endoscopic treatment is disclosed. The apparatus comprises an endoscopic insertion tube comprising an outer surface including an outer rail formed longitudinally thereon and extending along a portion of the insertion tube. The outer rail has a predetermined shape. The insertion tube comprises an inner channel formed therethrough. An endoscope apparatus for endoscopic treatment is disclosed. The apparatus comprises an endoscopic insertion tube without a working channel and an outer surface including at least one outer rail formed longitudinally thereon and extending along a portion of the insertion tube. The outer rail has a first predetermined shape. At least one medical device includes an outer wall having at least one mounting unit formed thereon along a portion of the length of the outer wall. The mounting unit has a second predetermined shape cooperable with the first predetermined shape. The second predetermined shape is formed to complement and slidably cooperate with the first predetermined shape of the outer rail for slidably attaching the medical device thereto.

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ENDOSCOPIC APPARATUS HAVING AN OUTER RAIL

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application serial no. 60/921,386, filed on April 2, 2007, entitled "ENDOSCOPIC APPARATUS HAVING AN OUTER RAIL," the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to endoscopic apparatus having outer rail guide systems.

[0003] Endoscopic devices have been commonly used for various procedures, typically in the abdominal area. Endoscopy is the examination and inspection of the interior of body organs, joints or cavities through an endoscope. Endoscopy allows physicians to peer through the body's passageways. An endoscopic procedure may be used to diagnose various conditions by close examination of internal organ and body structures and may also guide therapy and repair, such as the removal of torn cartilage from the bearing surfaces of a joint. A biopsy, a procedure involving tissue sampling for pathologic testing, may also be performed under endoscopic guidance. For example, endoscopic procedures include the following known procedures: gastroscopy, sigmoidoscopy and colonoscopy, esophago gastro duodenoscopy (EGD), endoscopic retrograde cholangiopancreatography (ERCP), and bronchoscopy.

[0004] An endoscope typically includes at least one separate port or working channel. Such port(s) may be used to introduce endoscopic instruments such as catheters, forceps, scissors, brushes, snares or baskets for tissue excision,

sampling, or other diagnostic and therapeutic work. The inner diameter of such working channels or ports may vary based on the instruments used during an endoscopic procedure, affecting the overall outer diameter size of the insertion tube of the endoscope. The differences in diameter typically affect the resulting size of the outer diameter of the endoscope. Moreover, as clinicians may use a number of various sized medical devices during an endoscopic procedure, they face challenges in maintaining wire guide position in certain anatomy, e.g., within the biliary tree, while executing an endoscopic procedure.

[0005] Thus, it is desirable to provide an improved endoscope apparatus that allows a clinician the ability to use various sizes of medical devices with one endoscope while maintaining longitudinal positioning within a patient's gastrointestinal anatomy.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention generally provides an outer rail endoscopic apparatus including an outer rail guide system that allows a clinician the ability to use various sizes of medical devices with one endoscope while maintaining longitudinal positioning within a patient's gastrointestinal anatomy.

[0007] In one embodiment, the present invention provides an endoscope apparatus for endoscopic treatment. The apparatus comprises an endoscopic insertion tube comprising an outer surface including an outer rail formed longitudinally thereon and extending along a portion of the insertion tube. The outer rail has a predetermined shape. The insertion tube comprises an inner channel formed therethrough. An endoscope apparatus for endoscopic treatment is disclosed. The apparatus comprises an endoscopic insertion tube without a working

channel and an outer surface including at least one outer rail formed longitudinally thereon and extending along a portion of the insertion tube. The outer rail has a first predetermined shape. At least one medical device includes an outer wall having at least one mounting unit formed thereon along a portion of the length of the outer wall. The mounting unit has a second predetermined shape cooperable with the first predetermined shape. The second predetermined shape is formed to complement and slidably cooperate with the first predetermined shape of the outer rail for slidably attaching the medical device thereto.

[0008] In another embodiment, the present invention provides an endoscopic apparatus having an outer rail system for endoscopic treatment. The apparatus comprises the endoscopic apparatus and at least one medical device including an outer wall having at least one mounting unit formed thereon along the length of the outer wall. The mounting unit is configured to slidably mate with the outer rail of the insertion tube for attaching the medical device thereto.

[0009] In yet another example, the present invention provides a method of using an endoscopic apparatus having an outer rail system for endoscopic treatment. The method comprises introducing the endoscopic apparatus in the gastrointestinal tract of a patient to an interventional location therein. The method further comprises maintaining position of the apparatus at the interventional location and introducing the medical device through the proximal end of the insertion tube. The method further comprises advancing the medical device beyond the distal end of the insertion tube for enhanced endoscopic treatment.

[0010] Further objects, features, and advantages of the present invention will become apparent from consideration of the following description and the appended claims when taken in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Figure 1A is an elevated view of an outer rail endoscopic apparatus in accordance with one embodiment of the present invention;

[0012] Figure 1B is a side view of the insertion tube of the apparatus of Figure 1A;

[0013] Figure 1C is a partial view of the insertion tube of the endoscopic apparatus of Figure 1A;

[0014] Figure 1D is a perspective view of a medical device that cooperates with the insertion tube of the endoscopic apparatus of Figure 1A;

[0015] Figure 2 is a partial exploded view of the apparatus of Figure 1A;

[0016] Figure 3A is an end view of the apparatus of Figure 1A;

[0017] Figure 3B is a cross-sectional view of the apparatus of 1A taken along line 3B-3B;

[0018] Figure 3C is a cross-sectional view of the apparatus of 1A taken along line 3C-3C;

[0019] Figure 3D is a cross-sectional view of the apparatus of 1A taken along line 3D-3D;

[0020] Figure 4 is a partial view of the apparatus of Figure 1A;

[0021] Figure 5 is an end view of the apparatus of Figure 4;

[0022] Figure 6 is an end view of the apparatus in accordance with another embodiment of the present invention;

[0023] Figure 7 is an end view of an apparatus in accordance with yet another embodiment of the present invention; and

[0024] Figure 8 is a flow chart of one method of using the endoscopic apparatus of Figure 1 in accordance with one example of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0025] The present invention generally provides an outer rail endoscopic apparatus that allows a clinician the ability to use various sizes of medical devices with one endoscope while maintaining longitudinal positioning within a patient's gastrointestinal anatomy. This feature also allows for a smaller or relatively reduced diametric size of the insertion tube. The reduced diameter of the insertion tube allows the clinician to be able to more easily perform an endoscopic treatment within a patient's anatomy (e.g., within the biliary duct) that otherwise would not be possible or would be a relatively high risk procedure. Each of the embodiments of the present invention comprises an insertion tube having an outer surface with an outer rail. Each outer rail is configured to cooperate with a mounting unit formed on a medical device (e.g., a wire guide or catheter) to be used during the endoscopic treatment. The medical device is slidably attachable to the side of the insertion tube at its proximal end and is distally advanced beyond the distal end of the insertion tube. This aspect allows enhanced positioning and treatment in areas of the anatomy otherwise unobtainable. Additionally, scope repairs would be reduced as the scope would not have to be sent out for repairs to the accessory channel.

[0026] Figure 1A illustrates an endoscopic apparatus 10 having an outer rail system for enhanced endoscopic treatment in accordance with one embodiment of the present invention. As shown, the endoscopic apparatus 10 comprises a flexible

insertion tube 12 and a control system 13 in communication with the insertion tube 12. As shown in Figures 1A and 1B, the flexible insertion tube 12 comprises an outer surface 14 including at least one outer rail 20 formed thereon. Preferably, the outer rail 20 comprises a first predetermined portion or shape 22 (discussed in greater detail below) to accommodate a complementary shape for attaching a medical device 24 thereto. In this embodiment, the outer rail 20 is formed on the outer surface 14 along the length of the insertion tube 12.

[0027] The outer rail 20 is formed on the outer surface 14 of the insertion tube 12 and replaces a conventional endoscopic working channel typically formed through the insertion tube 12 of an endoscope, thereby defining a smaller or reduced diametric size of the insertion tube 12. The outer rail 20 is configured to allow a medical device 24, e.g., a wire guide, to be slidably interlocked therewith and advanced relative to the insertion tube 12. The first predetermined shape 22 of the outer rail 20 may take on any suitable shape that allows a complementary or cooperating shape to be able to slide through and lock itself thereon. For example, as shown in Figures 2-5, the outer rail 20 of the insertion tube 12 is an interlocking rack that is configured to interlock with a complementing or cooperating shape formed along the length of a medical device 24, e.g., a wire guide or catheter. The medical device 24 may be distally advanced beyond the distal end of the insertion tube 12 to reach areas of an anatomy otherwise unobtainable by a conventional endoscope.

[0028] As mentioned above, the outer rail 20 replaces a conventional endoscopic working channel typically formed through the insertion tube 12. As shown, the insertion tube 12 does not have a conventional endoscopic working

channel. Rather, the insertion tube 12 comprises at least one inner channel in which endoscopic components are disposed, defining a reduced outer diameter occupied by the insertion tube 12. In this embodiment, the endoscopic components vary depending on the purpose of use for the endoscope. For example, the apparatus 10 includes any number of inner channels. In this embodiment, there are three inner channels shown in Figures 1A-5. As shown, an illumination channel 32 is formed through the insertion tube 12 through which a fiberoptic cable is inserted for the transmission of light from a light source. Moreover, a viewing channel 34 can also be provided with a fiberoptic cable for viewing purposes and a fluid channel 36 can be provided for application of suction at the surgical site. In another example, the inner channel may be a fluid channel, a light channel, and a camera channel formed through the insertion tube to allow for fluid, light, and a camera, respectively therethrough.

[0029] The endoscopic apparatus 10 shown in Figures 1A further comprises a control system 13 in mechanical and fluid communication with the insertion tube 12. The control system 13 is configured to control at least one of the endoscopic components. It is to be understood that any other suitable endoscopic operating control system 13 may be used with the insertion tube 12 described above without falling beyond the scope or spirit of the present invention. In one embodiment, the control system 13 includes an auxiliary port portion 123 having a proximal opening 124. The fluid channel 36 extends into the auxiliary port 123 by way of a fluid channel extension 119a. Each of the channels preferably opens at the distal or insertion end 113 of the flexible section 12 of the endoscopic apparatus 10.

[0030] The control system 13 of the endoscopic apparatus 10 shown in Figure 1A can be of many different types so long as it is in fluid and mechanical communication with the inner channels formed through the insertion tube 12 of the endoscopic apparatus 10. While most of the working components of these control systems 13 are similar, each may have a different configuration without falling beyond the scope or spirit of the present invention. For example, the proximal opening and the auxiliary port may differ amongst each other. Each of these specifically identified control systems, and other commercially available endoscopes, utilize different sealing members (not shown) at the proximal opening of the auxiliary port. It is understood that the various aspects of the present invention accommodate the secure attachment to various configurations and dimensions of a variety of endoscopes.

[0031] As shown, the endoscopic apparatus 10 further comprises at least one medical device 24 having an outer wall 42 comprising at least one mounting unit 44 formed thereon along the length of the outer wall 42. In this embodiment, the mounting unit 44 is configured to slidably mate with the outer rail 20 of the insertion tube 12 for slidably attaching the medical device 24 thereto. Preferably, the mounting unit 44 has a second predetermined portion or shape 46 cooperable with the first predetermined shape 22. The second predetermined shape 46 is formed to complement and slidably cooperate with the first predetermined shape 22 of the outer rail 20 for slidably attaching the medical device thereto.

[0032] In this example, this is accomplished by having the second predetermined shape 46 take on a complementing shape relative to the first predetermined shape 22. As shown in Figures 2-5, the medical device 24 slidably

interlocks with the insertion tube 12 due to the cooperating relationship between the outer rail 20 and the mounting unit 44.

[0033] In this example, the outer rail 20 is configured to proximally taper or distally flare longitudinally along the outer surface 14 of the insertion tube 12 to receive the mounting unit 44. As shown in Figures 1A, 2, and 3A-D, the mounting unit 44 is slidably received by the outer rail 20 at a proximal portion of the insertion tube 12. The mounting unit 44 extends distally along the insertion tube 12. Although not necessarily, the mounting unit 44 may extend to the distal end of the insertion tube 12 or may end proximal thereto (see Figures 1B-D). Moreover, in this embodiment, the mounting unit 44 extends proximally to a hub 45 through which other devices may be introduced through the endoscope.

[0034] As shown in Figure 1C, in one example, each of the outer rails 20 is formed longitudinally along the outer surface 14 of the insertion tube 12. Preferably, each of the outer rails 20 extends distally on the outer surface 14 to the distal end 113 of the insertion tube 12. In this embodiment, the outer rail 20 is formed with increased prominence distally along the outer surface, having an increased area or depth between each adjacent outer rail 20 at the distal end 113. This allows the mounting unit 44 (see Figure 1D) to slidably cooperate with the outer surface 14 and attach the medical device 24 to the insertion tube 12.

[0035] It is to be understood that each of the outer rails 20 and mounting units 44 may take on any suitable shape. This is possible so long as each outer rail 20 and its corresponding mounting unit 44 are configured to complement each other such that when engaged with each other in a slidably cooperating relationship, the two units are slidably interlocked with each other. Furthermore, depending on the

number of outer rails 20 formed on the insertion tube 12, the same number of medical devices 40 may be used with the insertion tube 12 during an endoscopic procedure.

[0036] In this embodiment, the insertion tube 12 comprises a proximal end 111 and a distal end 113. Preferably, each outer rail 20 is formed on the insertion tube 12 from the proximal end 111 to the distal end 113 so that the medical device 24 may be slidably introduced at the proximal end 111 and advanced beyond the distal end 113. This may be accomplished by any suitable manner, e.g., by having a tapered formation of the first predetermined shape 22 near the proximal end of the insertion tube 12. The medical device may then be introduced and advanced at the tapered formation to slidably engage the insertion tube 12. In use, e.g., a catheter, may be advanced to a location beyond the distal end of the insertion tube 12 to a stricture within the anatomy otherwise unobtainable with the outer diameter size of a conventional endoscope.

[0037] It is to be noted that the outer rail formed on the insertion tube may simply be one outer rail or a plurality thereof. In the embodiment shown in Figures 1a-5, the insertion tube comprises one outer rail formed along the length of the insertion tube. However, the embodiment provided in Figure 6 includes four outer rails 220. As shown, the insertion tube 212 comprises four outer rails 220 having first predetermined shapes radially formed about the outer surface of the insertion tube. In this embodiment, each of the outer rails 220 has a first predetermined shape that is the same as the others. As shown, the apparatus comprises an illumination channel 216 through which a fiberoptic cable is inserted for the transmission of light from a light source. Moreover, the apparatus comprises a

viewing channel 217 having a fiberoptic cable for viewing purposes and a third channel 218 for application of fluid or suction at the surgical site. A corresponding mounting unit having a second predetermined shape of a medical device (not shown) may be used to slidably attach to the outer rail in the similar manner as described above. Thus, a series of accessory channels would be able to engage the outer rail. This would allow the user flexibility during the procedure because the channel could be interchanged or swapped as desired.

[0038] The embodiment provided in Figure 7 includes two outer rails 320 formed on the insertion tube 312, each of which having a first predetermined shape that is the same as the other. A corresponding mounting unit has a second predetermined shape that may be used to slidably attach to the outer rail in the similar manner as described above. Thus, a series of accessory channels would be able to engage the outer rail. This would allow the user flexibility during the procedure because the channel could be interchanged or swapped as desired. In this embodiment, the apparatus also includes inner channels similar to the inner channels mentioned above.

[0039] Figure 8 illustrates a flow chart of one method 410 of using the endoscopic apparatus discussed above having an outer rail system for endoscopic treatment. As shown, the method comprises introducing the endoscopic apparatus in the gastrointestinal tract of a patient to an interventional location therein in box 412 and maintaining position of the apparatus at the interventional location in box 414. The method 410 further includes introducing a medical device through the proximal end of the insertion tube. The mounting unit is configured to slidably mate with the outer rail of the insertion tube for attaching a medical device thereto. In this

example, this may be accomplished by having the outer rail formed on the outer surface at a proximal portion of the insertion tube. The outer rail may be formed to proximally taper or distally flare to receive the mounting unit which may be slidably attached therewith. The mounting unit may extend proximally from the insertion tube to a port through which a medical device may be disposed for introduction thereof into the patient.

[0040] The method 410 further comprises advancing the medical device beyond the distal end of the insertion tube for enhanced endoscopic treatment that allows a clinician the ability to use various sizes of medical devices with one endoscope while maintaining longitudinal positioning within a patient's gastrointestinal anatomy in box 416.

[0041] The medical device is preferably provided separately from the endoscopic apparatus with the outer rail(s) already formed along the outer surface of the insertion tube. At a desired time during the use of the flexible insertion tube, the medical device can be slidably engaged along the length of the outer surface of the insertion tube. The medical device may be introduced at the proximal end thereof and then may be slidably advanced beyond the distal end of the insertion tube to a desired location within the anatomy of a patient. Additionally, scope repairs would be reduced as the scope would not have to be sent out for repairs to the accessory channel.

[0042] While the present invention has been described in terms of preferred embodiments, it will be understood, of course, that the invention is not limited thereto since modifications may be made to those skilled in the art, particularly in light of the foregoing teachings.

CLAIMS

1. An endoscope apparatus for endoscopic treatment, the apparatus comprising:

an endoscopic insertion tube without a working channel and comprising an outer surface including at least one outer rail formed longitudinally thereon and extending along a portion of the insertion tube, the outer rail having a first predetermined shape; and

at least one medical device including an outer wall having at least one mounting unit formed thereon along a portion of the length of the outer wall, the mounting unit having a second predetermined shape cooperable with the first predetermined shape; the second predetermined shape formed to complement and slidably cooperate with the first predetermined shape of the outer rail for slidably attaching the medical device thereto.

2. The apparatus of claim 1 wherein the at least one outer rail comprises first and second outer rails formed on the outer surface.

3. The apparatus of claim 2 wherein the at least one medical device comprises first and second medical devices, each having mounting units formed thereon and configured to mate with one of the first and second outer rails.

4. The apparatus of claim 1 wherein the insertion tube comprises a proximal end and a distal end, each outer rail being formed on the insertion tube from the proximal and distal ends so that the medical device may be slidably introduced at the proximal end and advanced beyond the distal end.

5. The apparatus of claim 1 wherein the at least one outer rail comprises four outer rails formed on the outer surface of the insertion tube.

6. The apparatus of claim 5 wherein the at least one inner channel comprises a fluid channel, a light channel, and a camera channel formed through the insertion tube for endoscopic treatment.

7. An endoscopic apparatus having an outer rail system for endoscopic treatment, the apparatus comprising:

an endoscopic insertion tube comprising an outer surface including at least one outer rail formed longitudinally thereon and extending along a portion of the insertion tube, the outer rail having a predetermined shape, the insertion tube comprising an inner channel formed therethrough; and

at least one medical device including an outer wall having at least one mounting unit formed thereon along the length of the outer wall, the mounting unit being configured to slidably mate with the outer rail of the insertion tube for attaching the medical device thereto.

8. The apparatus of claim 7 wherein the at least one medical device comprises first and second medical devices, each having mounting units formed thereon and configured to mate with one of the first and second outer rails.

9. The apparatus of claim 8 wherein the insertion tube comprises a proximal end and a distal end, each outer rail being formed on the insertion tube from the proximal and distal ends so that the medical device may be slidably introduced at the proximal end and advanced beyond the distal end for enhanced endoscopic treatment.

10. The apparatus of claim 8 wherein the at least one outer rail comprises four outer rails formed on the outer surface of the insertion tube.

11. The apparatus of claim 10 wherein the at least one inner channel comprises a fluid channel, a light channel, and a camera channel formed through the insertion tube for endoscopic treatment.

12. A method of using an endoscopic apparatus having an outer rail system for endoscopic treatment, the method comprising:

introducing the endoscopic apparatus in the gastrointestinal tract of a patient to an interventional location therein, the apparatus comprising:

an endoscopic insertion tube comprising an outer surface including an outer rail formed longitudinally thereon and extending along a portion of the insertion tube, the outer rail having a predetermined shape, the insertion tube comprising an inner channel formed therethrough;

maintaining position of the apparatus at the interventional location;

introducing a medical device through the proximal end of the insertion tube, the medical device comprising an outer wall having at least one mounting unit formed thereon along the length of the outer wall, the mounting unit being configured to slidably mate with the outer rail of the insertion tube for attaching the medical device thereto; and

advancing the medical device beyond the distal end of the insertion tube for enhanced endoscopic treatment.

13. The method of claim 12 wherein the outer surface of the insertion tube comprises first and second outer rails formed thereon.

14. The method of claim 12 wherein the at least one outer rail comprises four outer rails formed on the outer surface of the insertion tube.

15. The method of claim 14 wherein the at least one inner channel comprises a fluid channel, a light channel, and a camera channel formed through the insertion tube for endoscopic treatment.

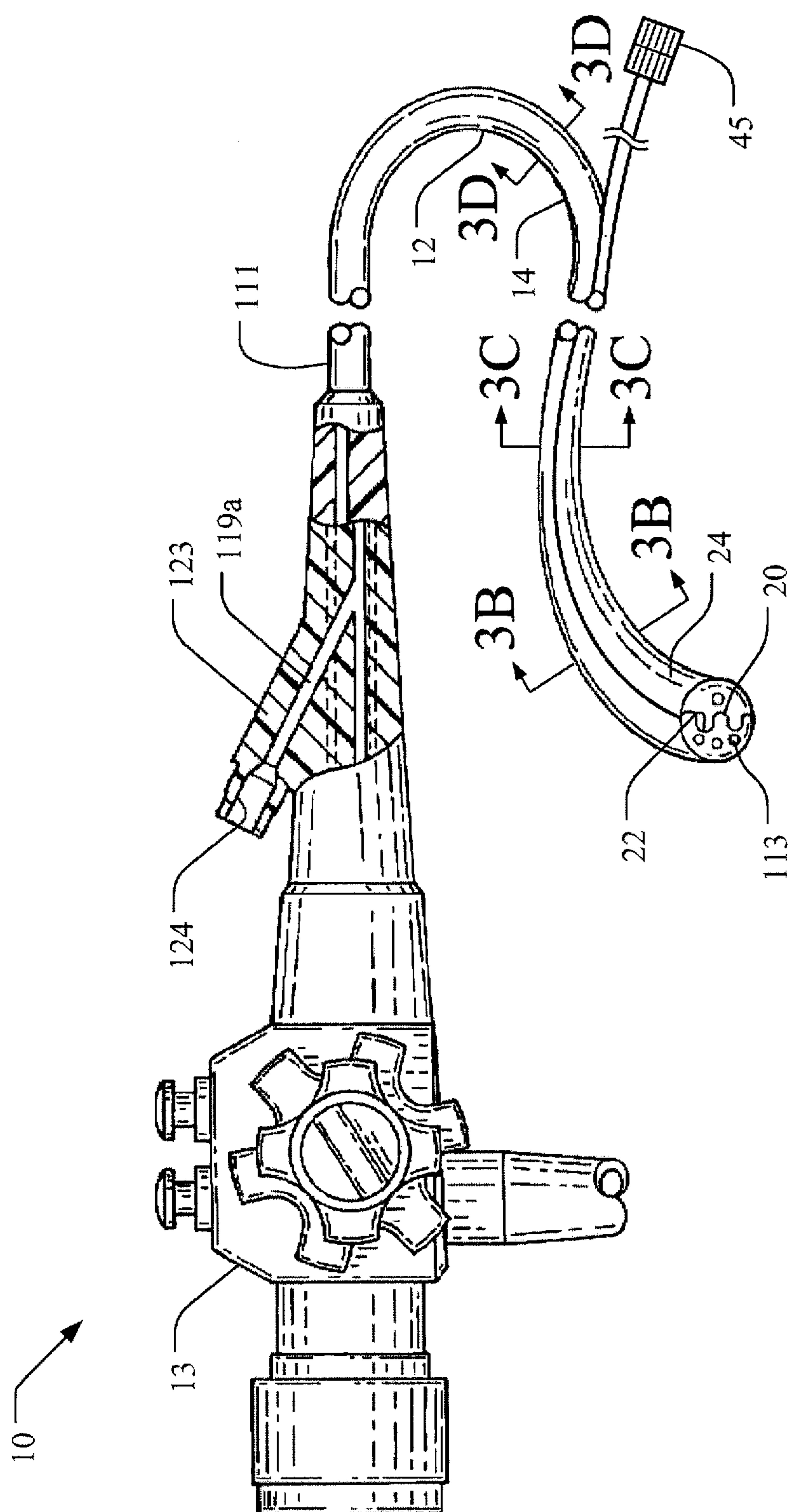


FIG. 1A

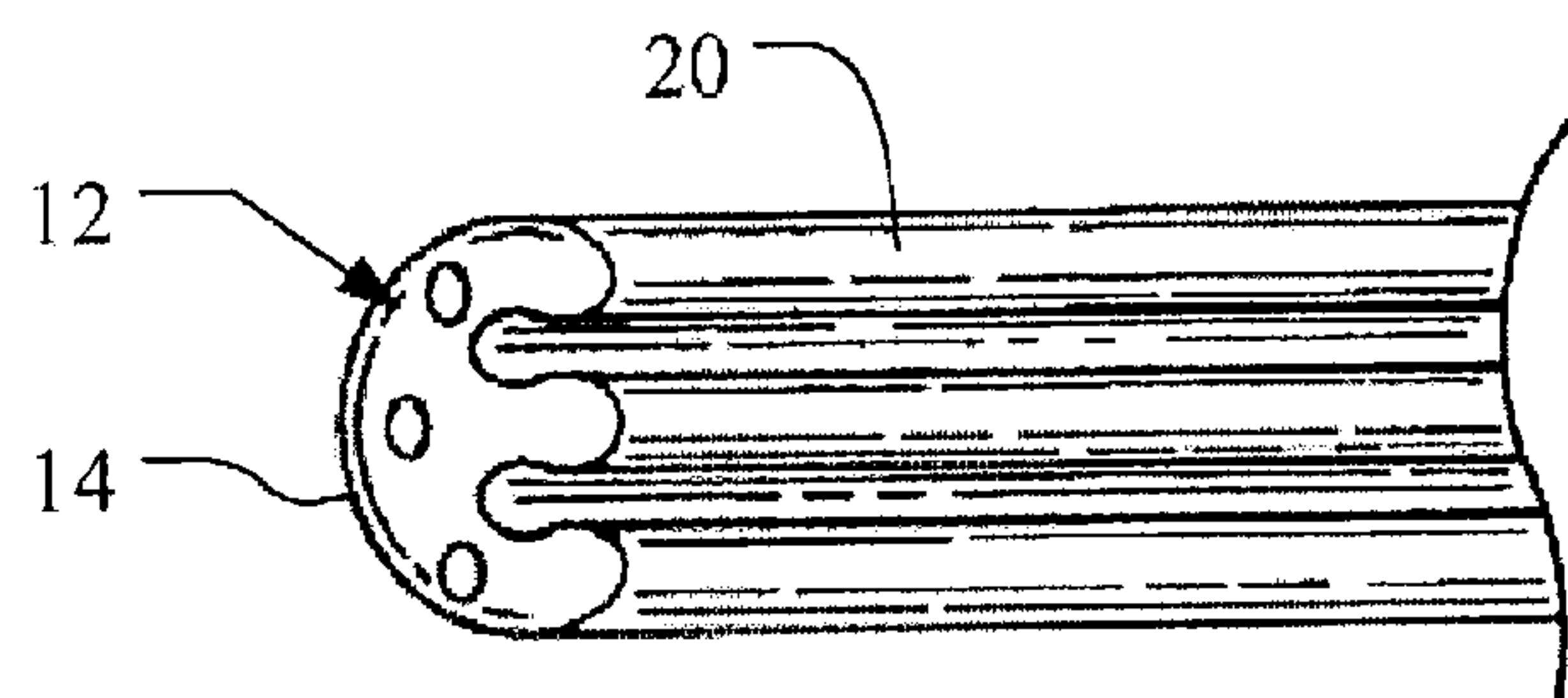


FIG. 1B

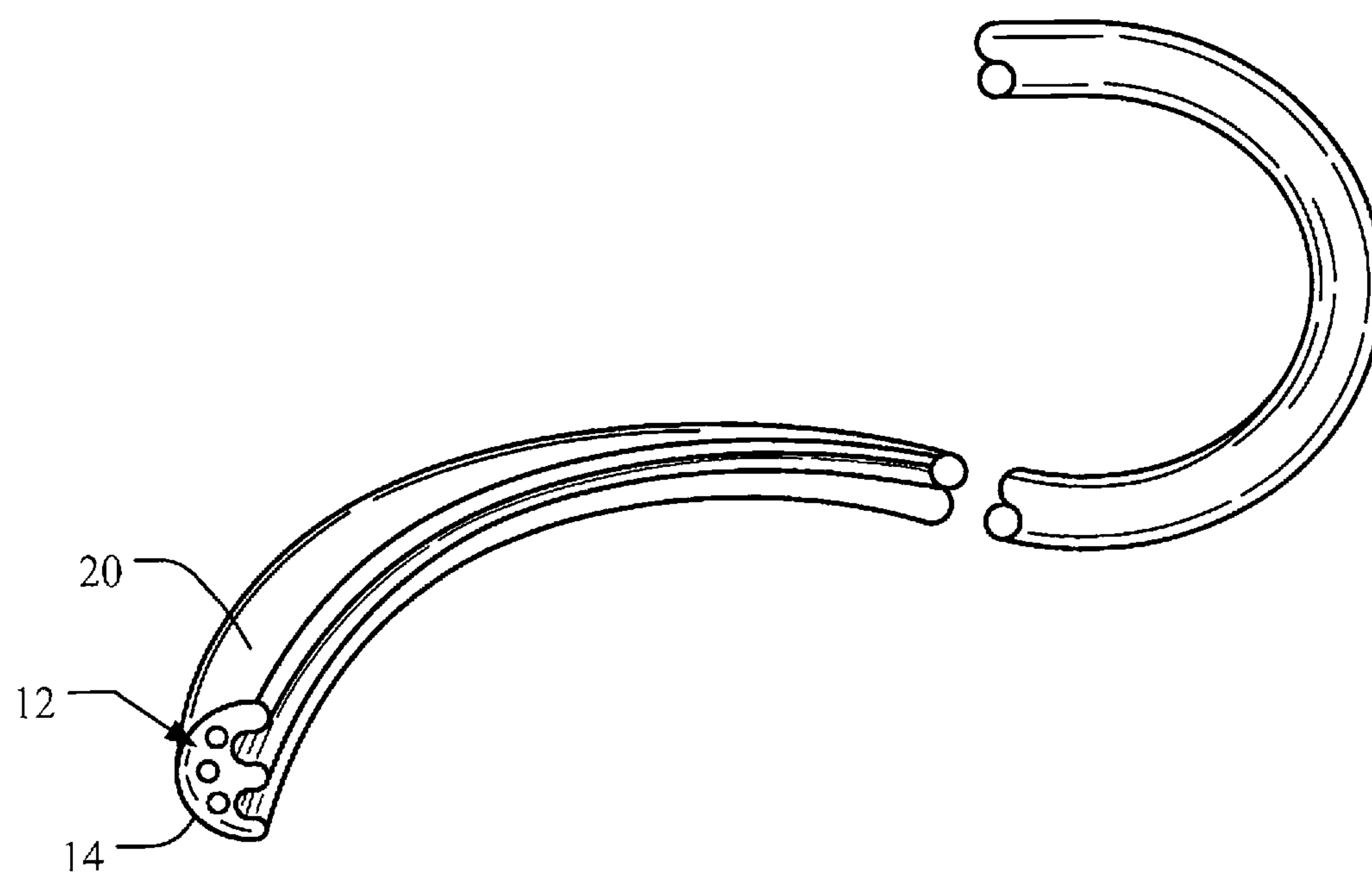


FIG. 1C

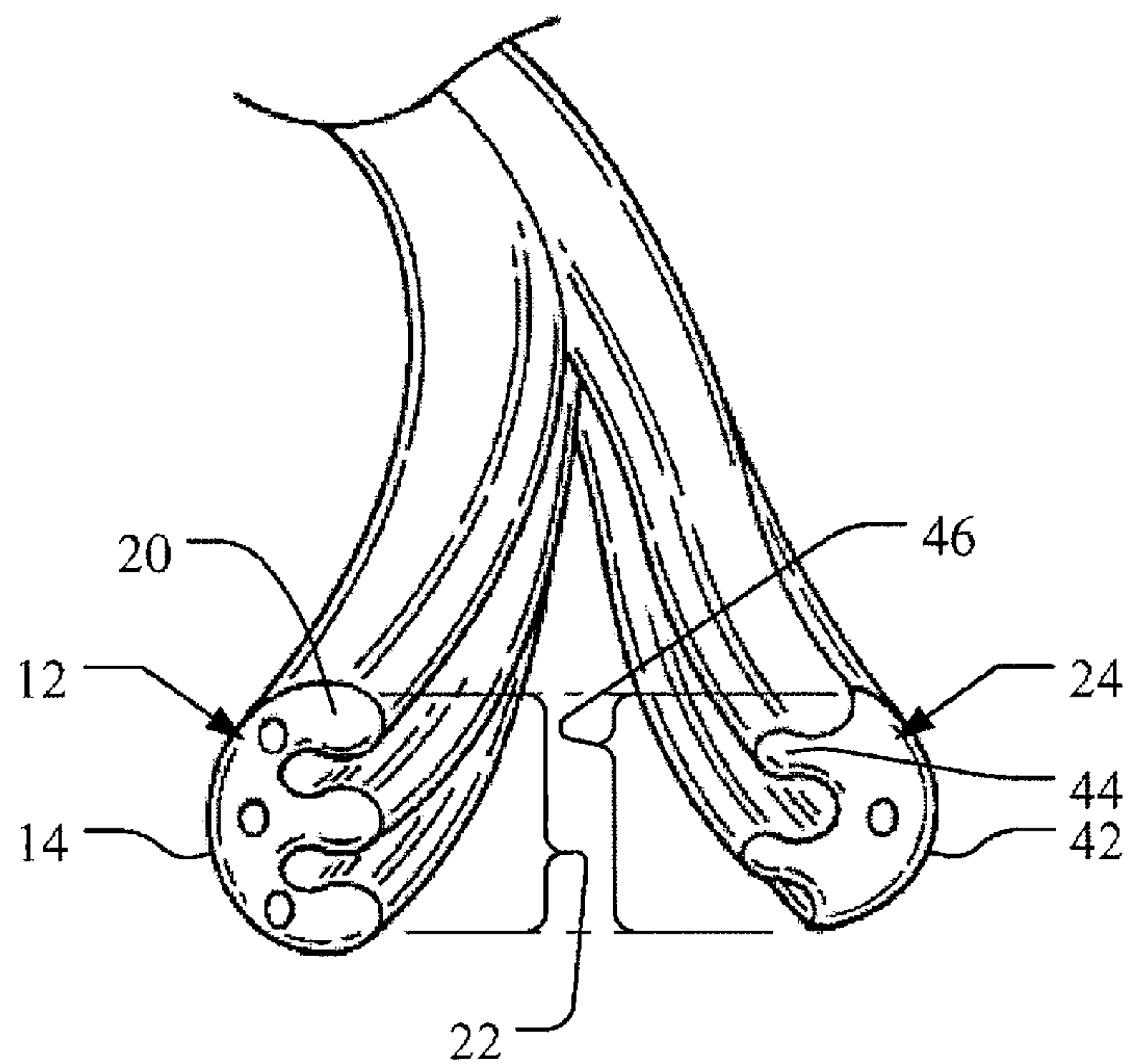
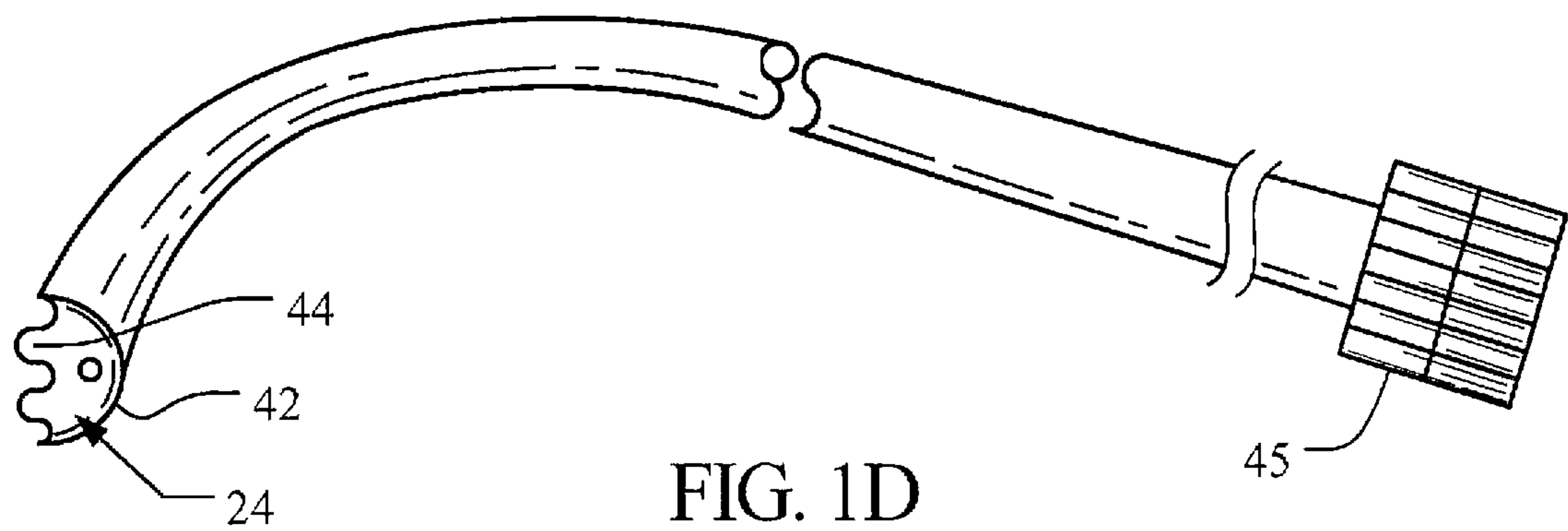


FIG. 2

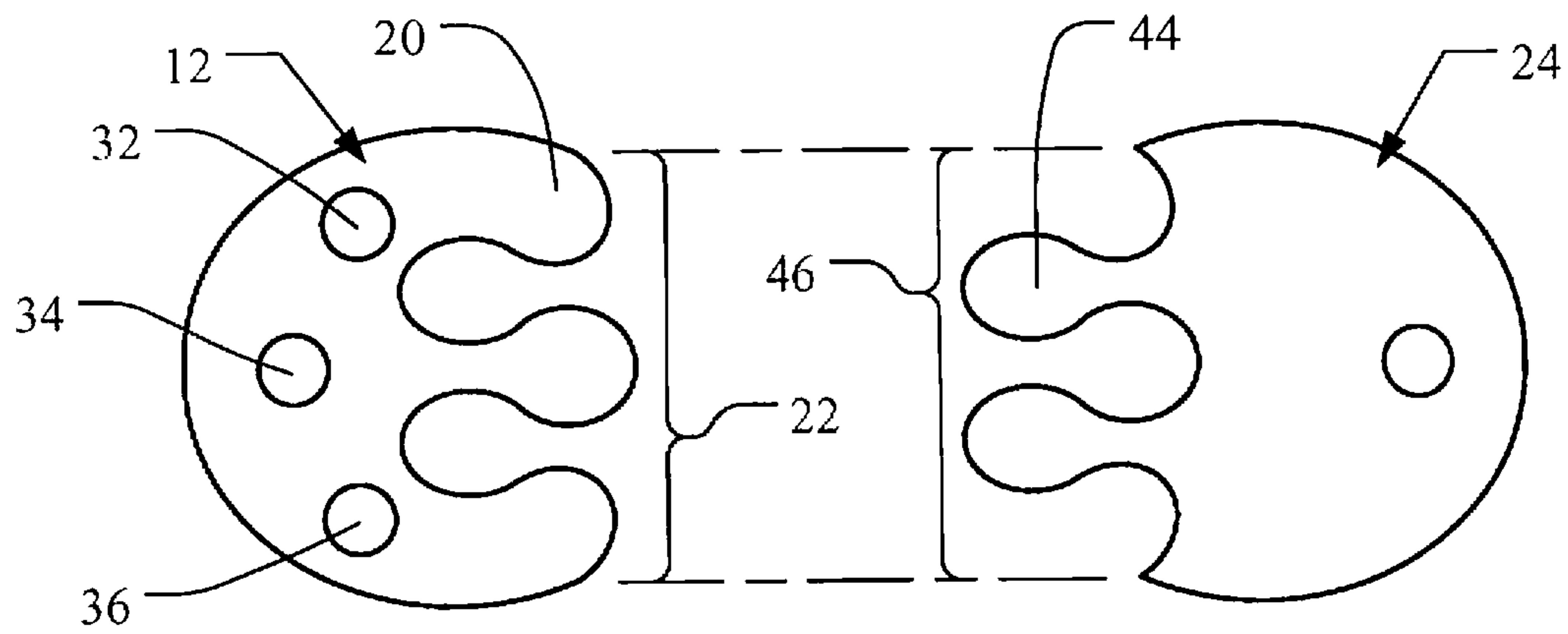


FIG. 3A

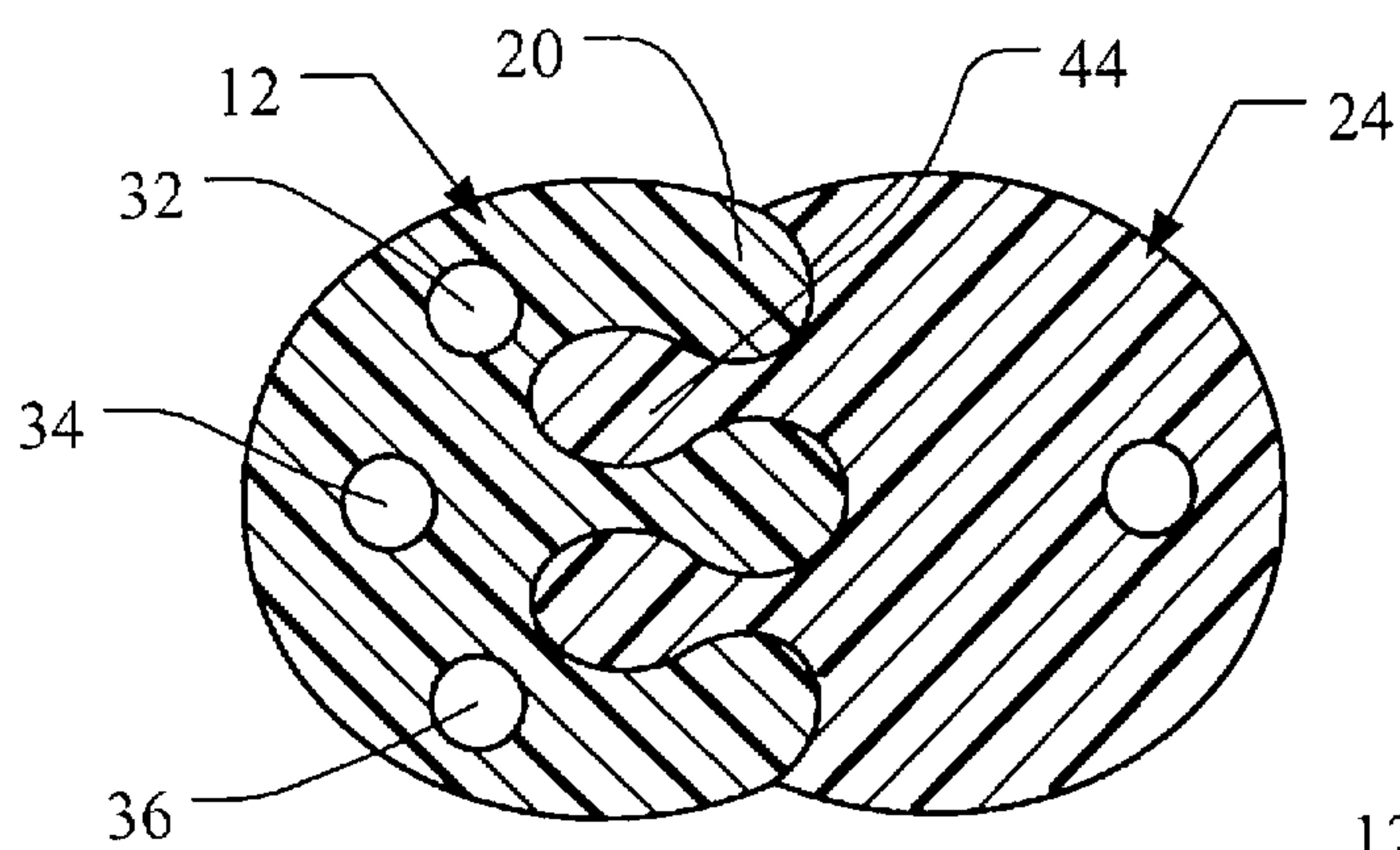


FIG. 3B

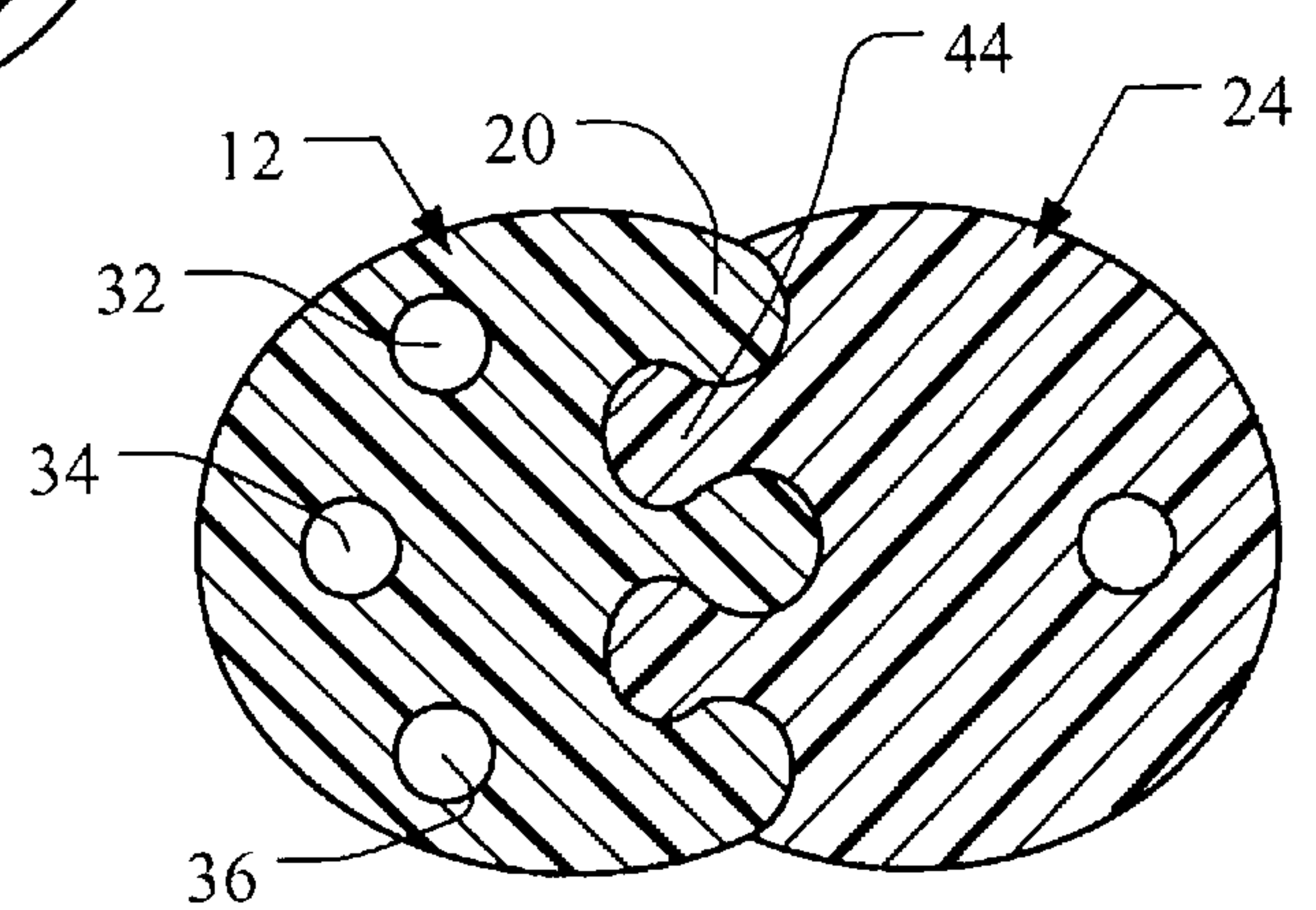


FIG. 3C

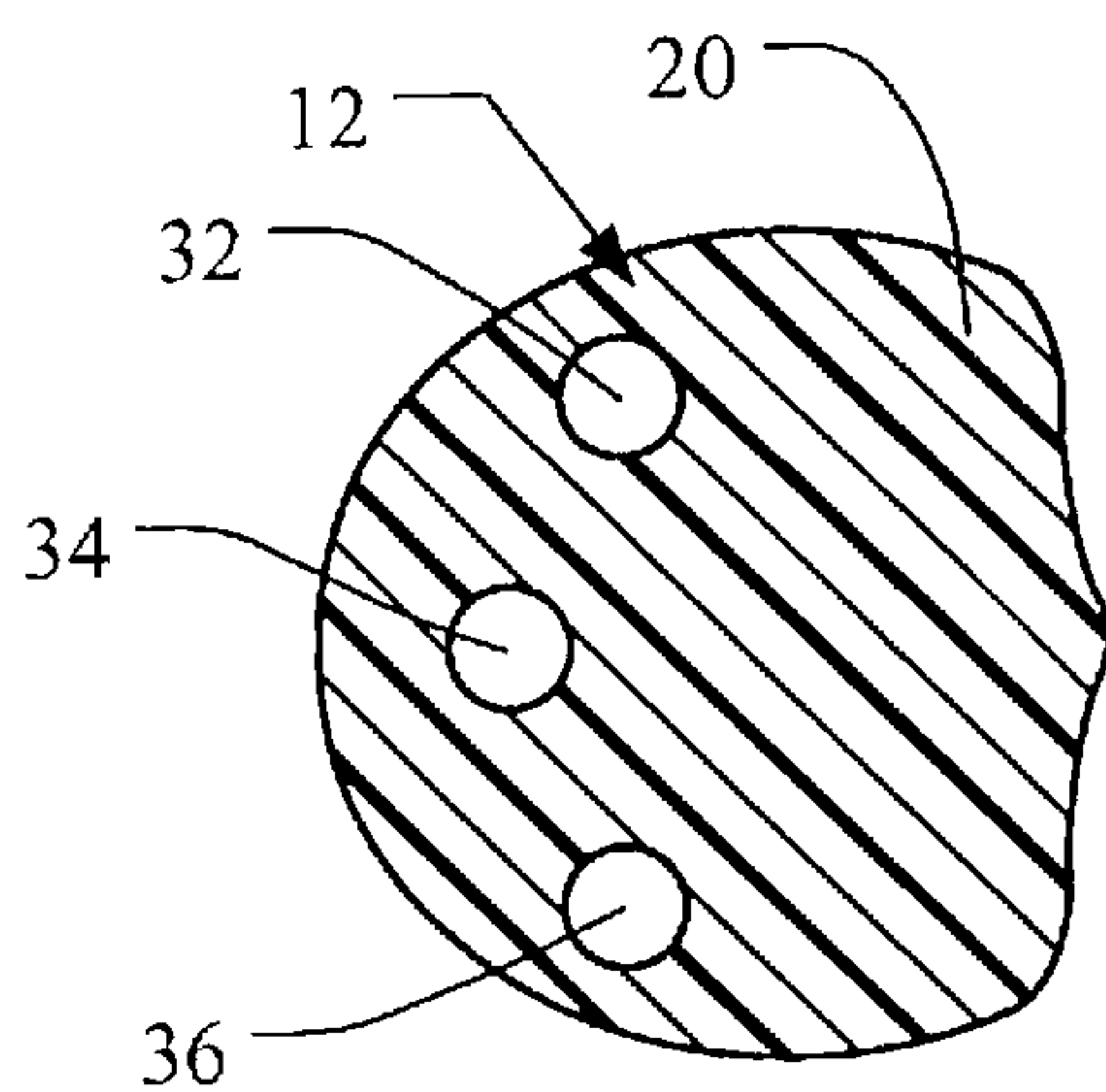


FIG. 3D

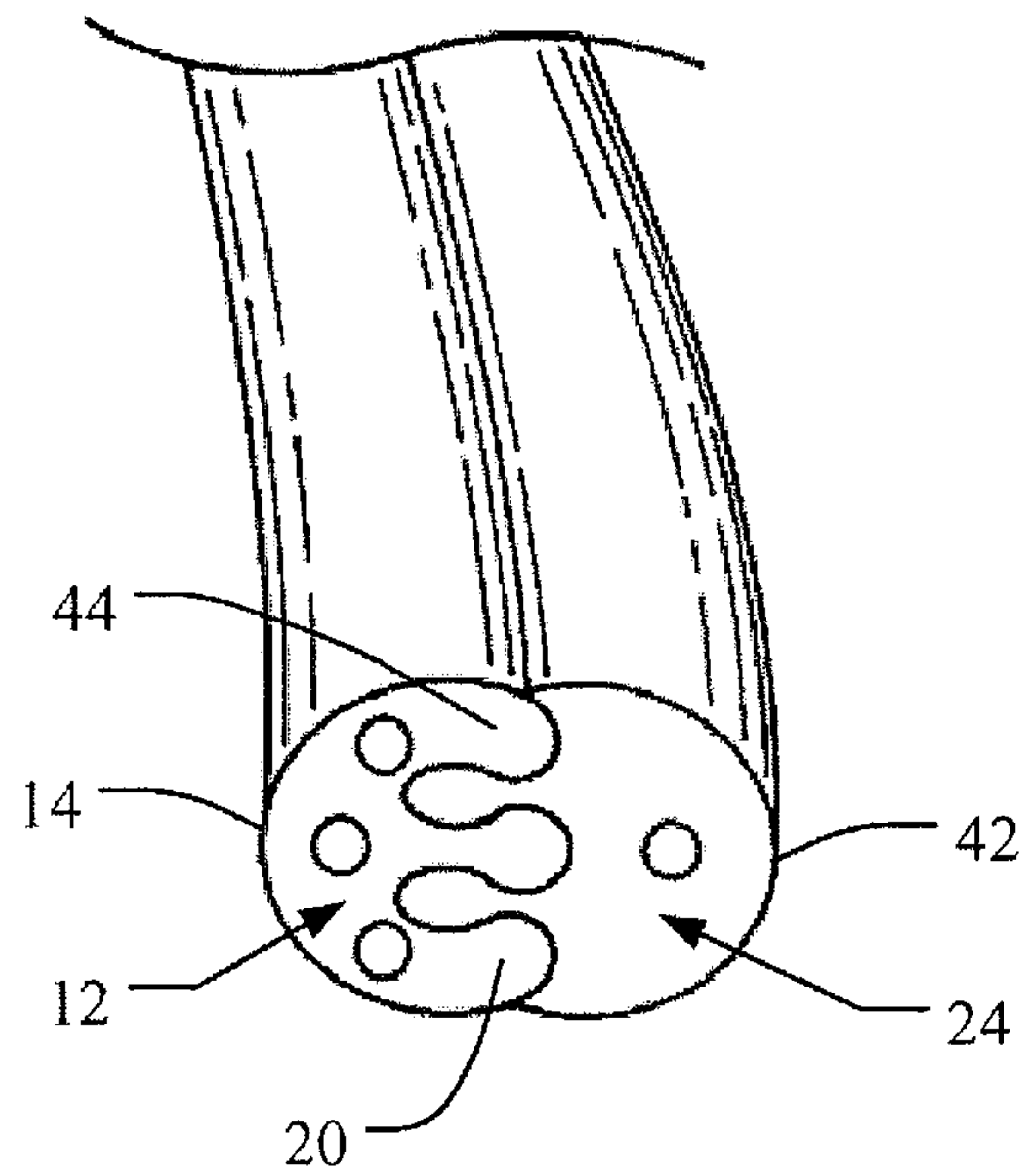


FIG. 4

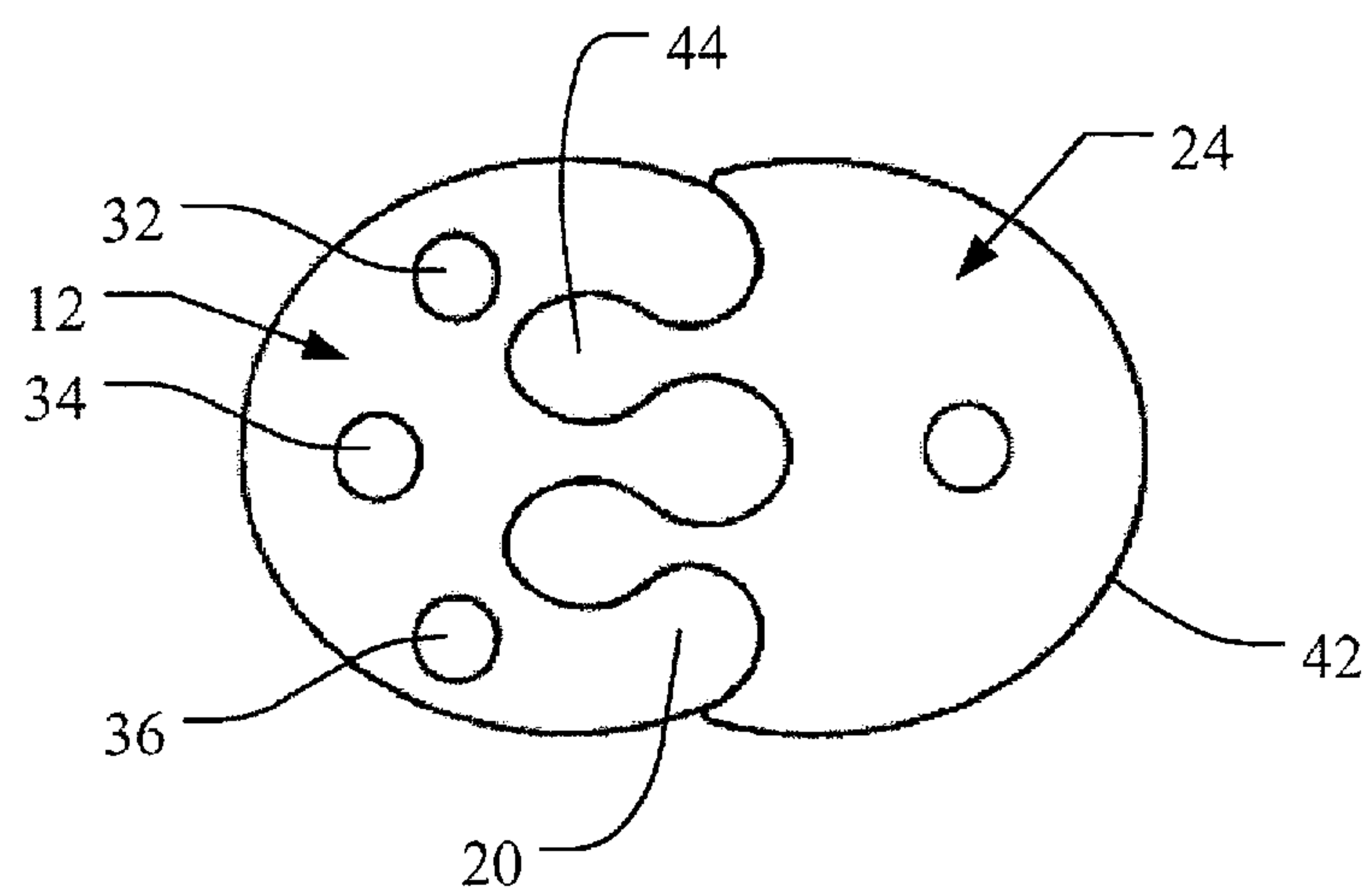


FIG. 5

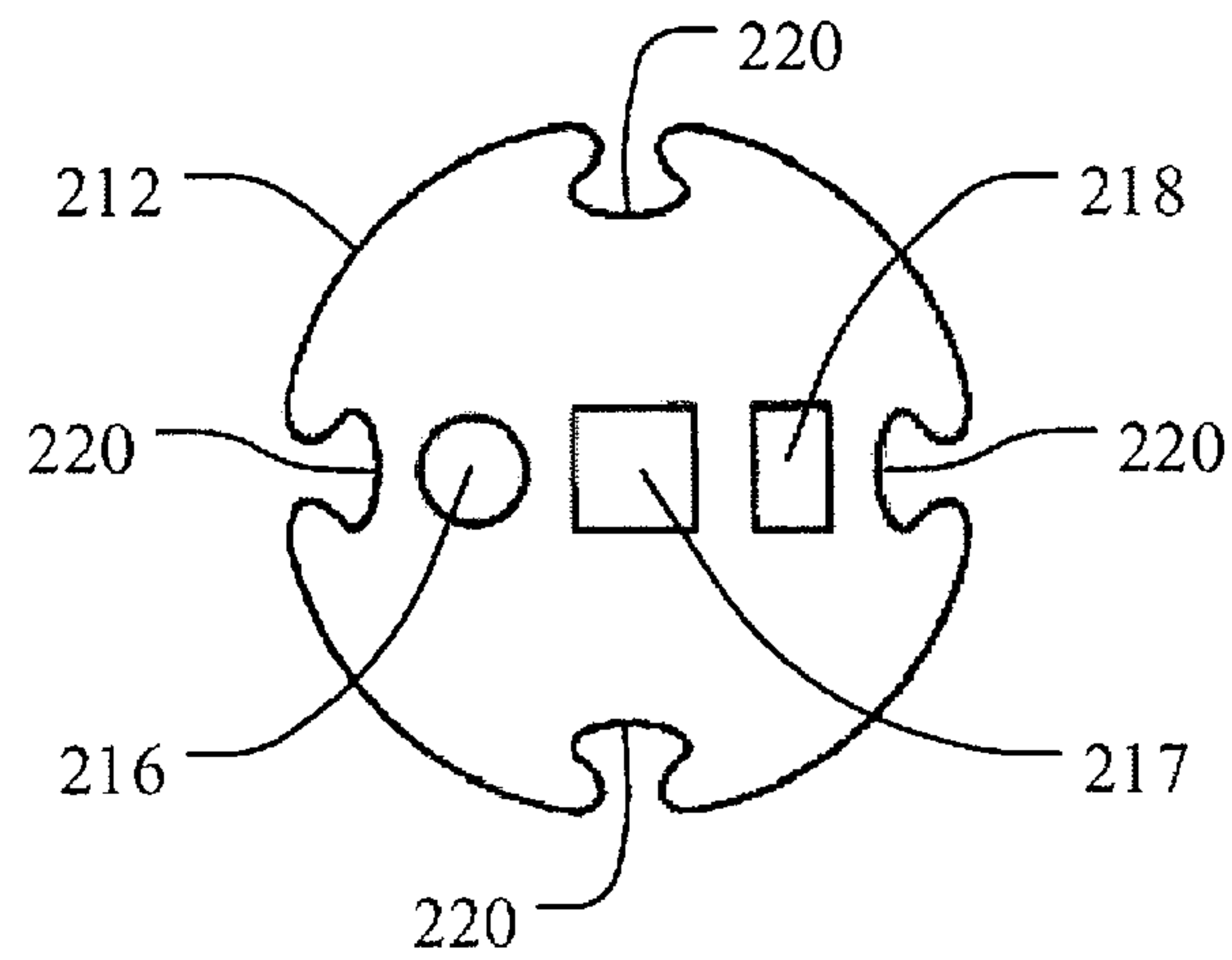


FIG. 6

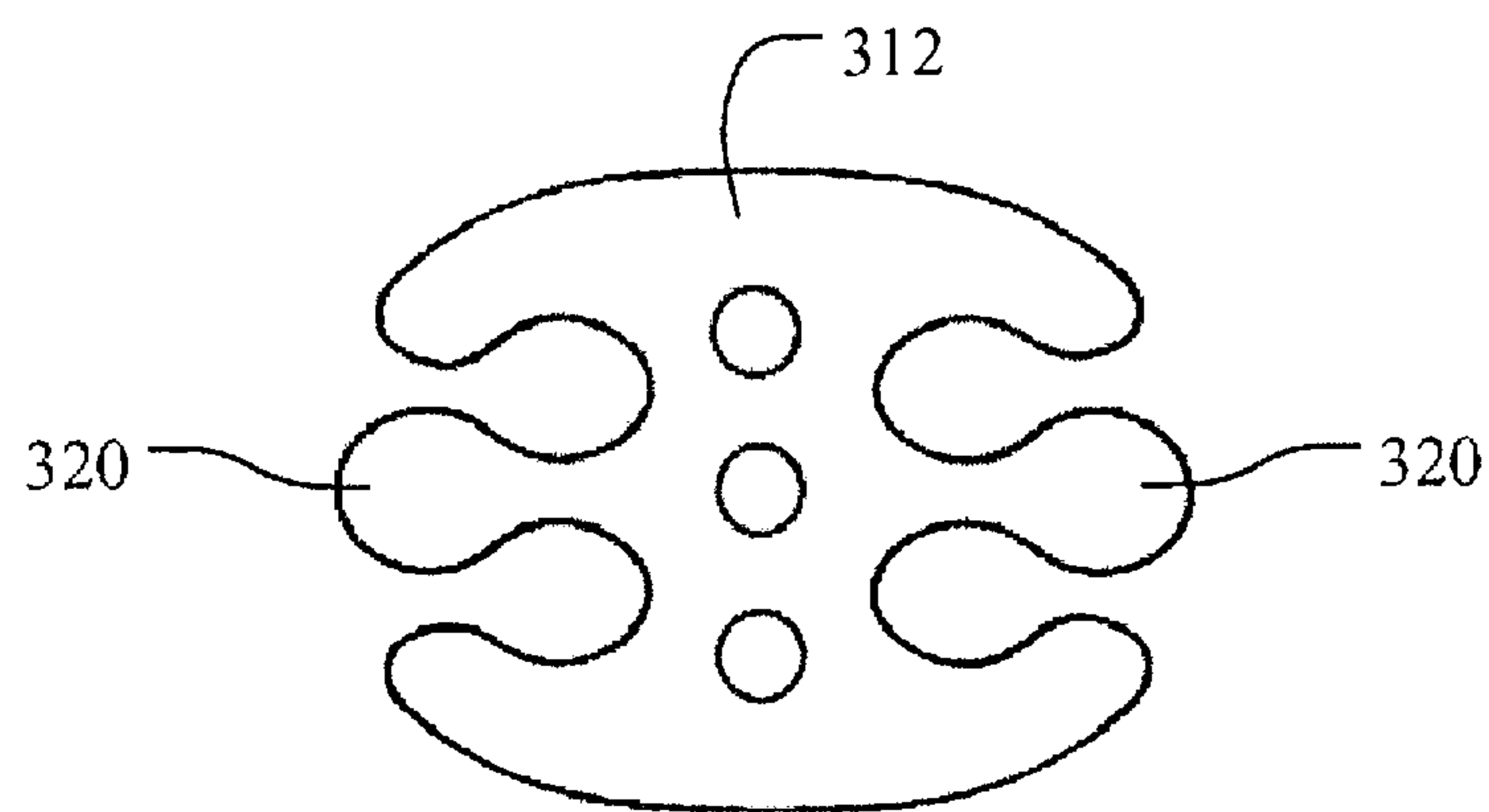


FIG. 7

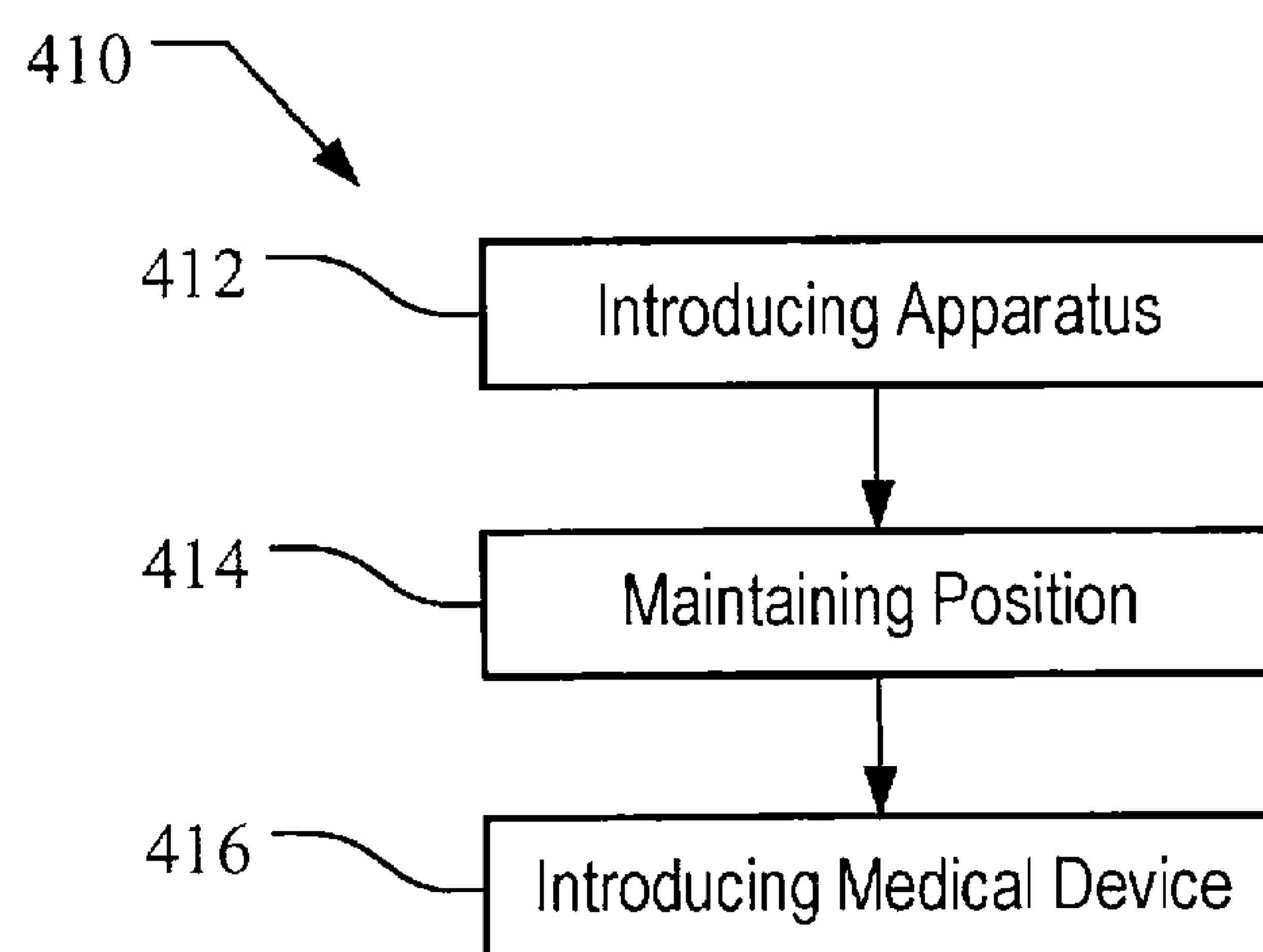


FIG. 8

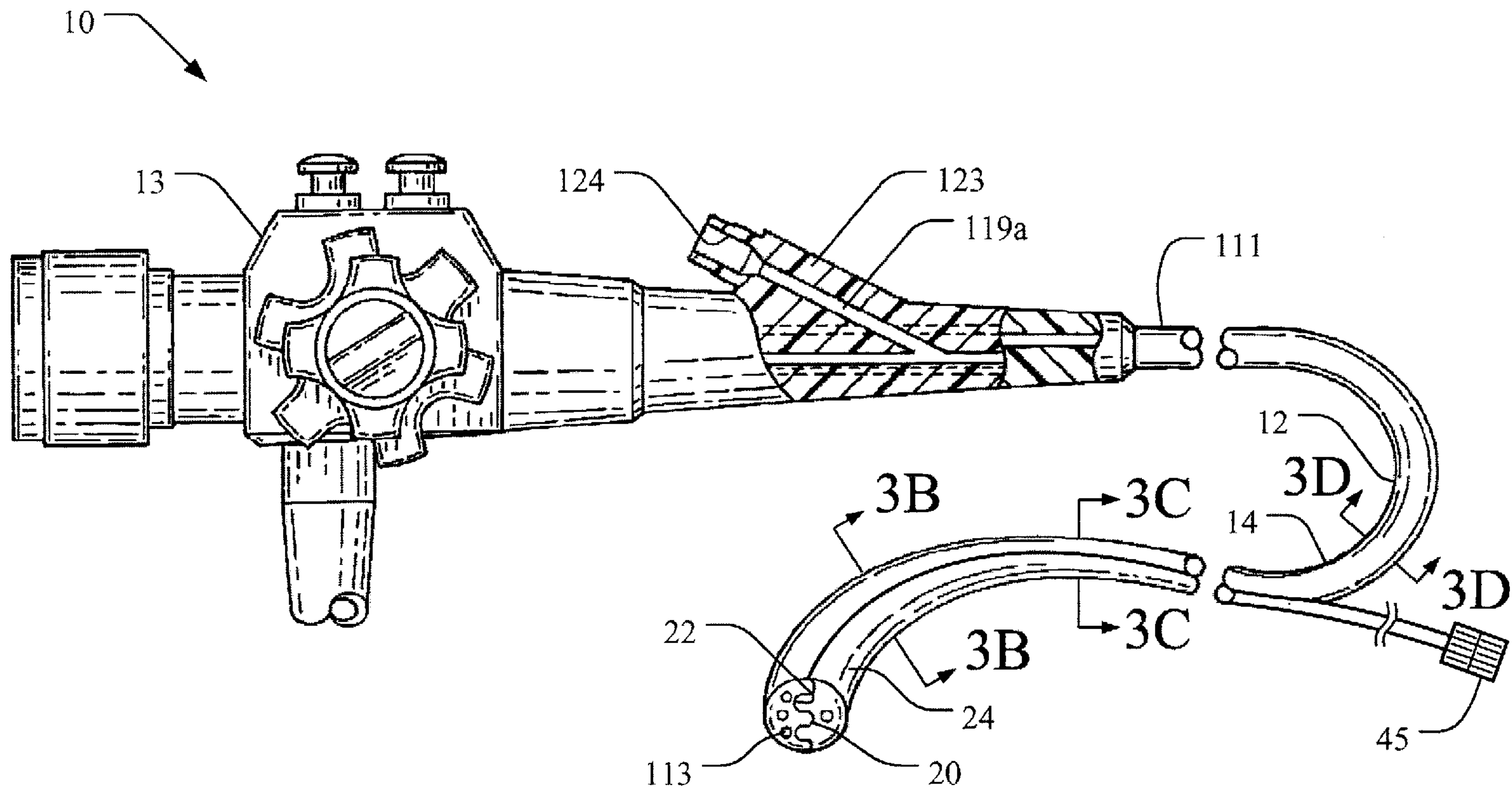


FIG. 1A